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## Appendix 1: 510(k) Summary per 21CFR §807.92

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**Submitter's  
information**

Stereotaxis, Inc.  
4320 Forest Park Ave, Suite 100  
St. Louis, MO 63108  
Contact: Dennis Pozzo, Regulatory Affairs Master Specialist  
Phone: 314-678-6136  
September 25, 2009

JAN 21 2010

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**Device/  
classification  
name**

- Device Name:
  - Odyssey™ Workstation
- Classification/Common name:
  - Steerable Catheter Control System
- The marketed device(s) to which substantial equivalence is claimed:
  - Odyssey™ Workstation

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**Device  
description**

The Odyssey Workstation is an optional (large screen) display and user interface package which allows the clinician to view multiple diagnostic tool screens (e.g. Navigant, X-Ray, ECG, Carto, etc.) in the catheter lab. on one large flat panel monitor to view and interpret a variety of sources on a single screen. There are multiple view formats available, and the clinician can customize layouts to facilitate their specific workflow.

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**Intended use**

The Odyssey Workstation is an optional display and user interface package designed to consolidate the point of control of the Catheterization Lab.

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*Continued on next page*

**Appendix 1: 510(k) Summary per 21CFR §807.92, Continued****Technological characteristics**

The table below lists device characteristics of the proposed Odyssey Workstation vs. the predicate Navigant NWS.

Device Characteristic	Odyssey Workstation in Catheter Lab w/Niohe MNS (predicate)	Odyssey Workstation in Catheter Lab w/o Niohe MNS
Display (monitor) Size	46"	Optional displays: 23", 24", 42", 46" and 56"
Pixel Resolution	1920 x 1080	23" and 24" displays – 1920 x 1200 42" and 46" displays – 1920 x 1080 56" display – 3840 x 2160
Allowable Video Sources	12	12
Allows control of connected video sources.	Yes	Yes
Keypad controls only Navigant	Yes	No
Allows control of video sources' native keypad and mouse.	Yes	Yes
Displays graphics & verbiage of connected video sources.	Yes	Yes
Allows the user to choose between predetermined layout/scripts or a customizable display.	Yes	Yes
Allows user interaction between video sources on the display.	Yes	Yes
Save display layout	Yes	Yes

**Performance data**

Based upon the documentation presented in this 510(k) it has been demonstrated that the Odyssey Workstation is safe and effective when used in standard catheter labs.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

JAN 21 2010

Stereotaxis, Inc.  
c/o Mr. Dennis Pozzo  
Regulatory Affairs Master Specialist  
4320 Forest Park Avenue, Suite 100  
St. Louis, MO 63108

Re: K093092

Trade/Device Name: Odyssey Workstation  
Regulation Number: 21 CFR 870.1425  
Regulation Name: Programmable Diagnostic Computer  
Regulatory Class: II (two)  
Product Code: DQK  
Dated: December 18, 2009  
Received: December 22, 2009

Dear Mr. Pozzo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

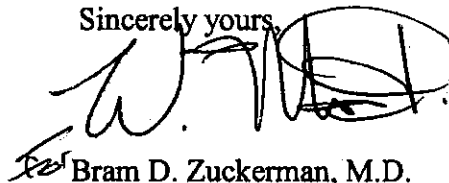
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', is written over a circular stamp that is partially obscured by the signature.

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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## Appendix 2: Indications for Use Statement

**Statement**

The indications for Use Statement:

510(k) Number: K 093092

Device Name: Odyssey™ Workstation

The Odyssey Workstation is an optional display and user interface package designed to consolidate the point of control of the Catheterization Lab.

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON  
ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Cardiovascular Devices

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